

REMARKS

Claims 1-77 and 80 are pending in the application. Claims 78-79 are cancelled without prejudice or disclaimer. The office action is discussed below:

Obviousness Rejections:

On pages 2-7 of the office action, the examiner maintained the obviousness rejections of claims 1-77 and further rejected claim 80 as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and further in view of Parth *et al.* (2002), and/or Burstein *et al.* (US 6,629,198), and/or Ylanen *et al.* (US 6,517,857). On pages 7-9 of the office action, the examiner states that Lidgren teaches that "the antioxidant doped UHMWPE is subjected to radiation in order to promote cross-linking" and "it is generally well known to irradiate UHMWPE in order to induce controlled cross-linking". According to the examiner, Lidgren teaches that "the UHMWPE powder dope with antioxidant is compression molded into blocks (consolidated) and then processed into medical implants from said blocks" (see col. 6, lines 1-5). Applicants respectfully traverse these rejections.

First, applicants refer to the arguments submitted in response to previous office action. Herein, applicants further submit that the examiner has not appreciated the differences in properties that result from doping before versus after consolidation of UHMWPE powder. Rather, the examiner has stated that "selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results...." In this vein, the examiner on page 3 of the office action refers to Hahn as disclosing that "consolidating a polymeric material (UHMWPE) and doping said consolidated polymeric material with antioxidant as an equivalent alternative to doping the polymeric material" Thus, the examiner believes that the skilled person would believe that doping a consolidated polymeric material is essentially the same as doping the unconsolidated, polymeric material (*i.e.* powder, particles or flakes). Again, applicants respectfully disagree with the examiner and point out that the examiner has not addressed the new and unexpected results of the instant methods and the undesirable color change and lower wear resistance that that result from the Hahn and Lidgren processes.

First, Example 4 of the captioned application is like Lindgren and Hahn, and concerns UHMWPE powder samples that were doped with Vitamin E prior to consolidation and irradiated with 100 kGy of gamma irradiation. Pin-on-disk wear

testing showed that wear rate was reduced from the typical 8 mg per million cycles (no irradiation and no Vitamin E) to a range of 2 - 5 mg per million cycles. Example 15, on the other hand, describes the irradiation (100 kGy gamma irradiation) and doping of consolidated UHMWPE with Vitamin E. As shown in Table 2, the pin-on-disk wear rate was reduced to 0.82 mg per million cycles when consolidated UHMWPE was doped, which is significantly less than half the wear rate of the lowest end of the range from Example 4. Accordingly, applicants' approaches for doping consolidated UHMWPE, rather than UHMWPE powder, provide significantly and unexpectedly enhanced wear resistance.


Moreover, Lidgren's and Hahn's mixing of the resin powder, flakes, or particles with vitamin E and consolidation thereafter subjects the vitamin E to the deleterious effects of heating in normal atmospheres, which results in degradation of vitamin E and changes in color of the polymeric material to yellow, neither of which is desirable in the industry. See Examples 1 and 2 of the captioned application.

Accordingly, the claimed invention provides UHMWPE with new and unexpectedly advantageous properties, and therefore applicant's invention is not obvious as per the requirements of MPEP §2144(IV)(C). Accordingly, applicants respectfully request withdrawal of the obviousness rejection.

REQUEST

Applicants submit that the claims 1-77 and 80 are in condition for allowance and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,



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Date

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